

ATTORNEY DOCKET NO. 02-062 (ANSI01-00010)
U.S. SERIAL NO. 09/822,728
PATENT

REMARKS

Claims 3-18 are pending in the application.

Claims 3-18 have been rejected.

Reconsideration of the Claims is respectfully requested.

I. REJECTION UNDER 35 U.S.C. § 112

Claims 3-18 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, and Claims 3-18 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The rejections are respectfully traversed.

The Office Action claims that the two regions (and four regions) and their respective electrical connections are not found in the specification. To the contrary, the Specification clearly provides support for this subject matter, including the following passages:

... Lead 10 includes a lead body 12, four band electrodes 14 and four connector bands 15, for exemplary purposes. ... Typically, one or more band electrodes 14 and one or more band connectors are provided. Lead 10 is generally configured to transmit an electric signal ... Thus, band electrodes 14 are typically located at the distal end of lead 10. Lead body 12 includes a flexible lead insulator surrounding one or more conductors. The conductors are electrically coupled to band electrodes 14 at the distal end and band connectors 15 at the proximal end of lead 10. (emphasis added)

See, Specification, Page 5, line 24 thru Page 6, line 5; Figure 1.

Figure 2 illustrates the details of an embodiment of the connection between a conductor 22 and band electrode 14 in accordance with the present invention. ... Band electrode 14 is connected [to] lead body 12 at welding

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regions 20 by a weld through band electrode 14 to electrically connect the band to conductive pad 24. . . . Band electrode 14 is connected to the same conductor 22 twice for exemplary purposes. (emphasis added)

See, Specification, Page 7, lines 15-26; Figures 2 (illustrating two regions, and two connections from the electrode 14 to the conductor 22).

Figure 3 illustrates a top view of a lead body having the insulating material removed to form welding region 20 by exposing conductor 22. Welding region 20 provides access to conductor(s) 22 for electrically connecting band electrode 14 to conductor 22. . . .

Referring to Figures 2 and 3, . . . Figure 2 shows a side view of a cross-section of two grooves 20 that expose two regions of the same conductor 22. . . . (emphasis added).

See, Specification, Page 7, line 28 thru Page 9, line 12; Figures 2 and 3.

Applicant's specification adequately describes and enables two regions and connections to a conductor, as set forth in the claims. Moreover, one of ordinary skill in the art will readily understand that Figures 2 and 3 illustrate a plurality of regions 20 (or one) to allow for connection of the band electrode to a conductor, and that there may be similar and additional regions 20 for connection to a second conductor (Applicant's specification discloses four band electrodes, four connector bands, and multiple conductors for connecting the band electrodes to the connector bands). The Office Action appears to confuse "two regions for electrode placement" with the Applicant's two regions formed by removal of the insulator whereby an electrode is electrically connected to a conductor through the two regions.

Accordingly, the Applicant respectfully requests withdrawal of the § 112 rejections of Claims 3-18.

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II. REJECTION UNDER 35 U.S.C. § 103

Claims 3-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kallok, et al (US 4,355,646) in view of Winkler (US 5,417,208). The rejection is respectfully traversed.

In *ex parte* examination of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness is established does the burden shift to the applicant to produce evidence of nonobviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or

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motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP § 2142.

Kallok and Winkler appear to simply disclose leads having multiple electrodes with each electrode having an electrical connection between the electrode and the conductor. Both Kallok and Winkler fail to disclose a lead having first and second regions each formed by removal of a portion of the insulator, and whereby an electrode is electrically connected to a conductor through the first region and also electrically connected to the same conductor through the second region.

Therefore, none of the references, either alone or in combination, disclose, teach or suggest Applicant's claimed invention. Moreover, combination of the two references would not render Applicant's claimed invention, as none of the references appear to disclose a lead having multiple regions to provide electrical connections between an electrode and a conductor.

Accordingly, the Applicant respectfully requests withdrawal of the § 103(a) rejection of Claims 3-18.

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III. OBJECTION TO THE SPECIFICATION

The Specification is objected to because it appears that the word "chord" should be "cord". Applicant respectfully submits that, with respect to anatomy, the word "cord" can be used interchangeably with "chord." Accordingly, Applicant has not amended the specification. However, in the event the next Office Action maintains this objection, Applicant will either provide documentation support for its position, or will amend the specification.

IV. CLAIM OBJECTIONS

The Office Action asserts that the previous amendment introduced new matter into the application. This objection is respectfully traversed. For the reasons set forth above in response to the 112 rejections, the amendments to the claims are supported by Applicant's specification. Accordingly, Applicant respectfully requests withdrawal of this objection.

V. CONCLUSION

As a result of the foregoing, the Applicant asserts that the remaining Claims in the Application are in condition for allowance, and respectfully requests an early allowance of such Claims.

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If any issues arise, or if the Examiner has any suggestions for expediting allowance of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at rmccutcheon@davismunck.com.

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

DAVIS MUNCK, P.C.

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Robert D. McCutcheon
Registration No. 38,717

P.O. Box 802432
Dallas, Texas 75380
(972) 628-3632 (direct dial)
(972) 628-3600 (main number)
(972) 628-3616 (fax)
E-mail: rmccutcheon@davismunck.com